Remarks

Upon entry of the foregoing amendment, claims 1, 2, 4, 9-14, 19-26, 28, 30-44, 47-77, 80, 81, 87, 90, 93-96, 98, 99, 102-127 and 128-136 are pending in this application.

Claims 32-34, 37, 38, 42, 43, 47-54, 59-71, 73 and 74 have been withdrawn from examination as being directed to a non-elected invention.

Claims 3, 5-8, 15-18, 27, 29, 45, 46, 78, 79, 82-86, 88, 89, 91, 92, 97, 100 and 101 are canceled without prejudice or disclaimer. Applicants reserve the right to pursue claims directed to the canceled subject matter in a continuing or divisional application.

Claims 128-136 are newly added.

Claims 1, 2, 4, 9-14, 19-26, 28, 30-31, 35, 36, 39-41, 44, 55-58, 72, 75-77, 80, 81, 87, 90, 93-96, 98, 99, 102-127 and 128-136 are currently under examination.

Claims 1, 4, 9-14, 19-26, 28, 30, 31, 35, 36, 39-41, 44, 55-58, 72, 75-77, 80, 81, 87, 90, 93-96, 98 and 99 have been amended.

Claims 1, 80, 93, 102, 110, 112, 115 and 117 are the independent claims.

Support for the amendments to claim 1 is found, for example, as follows:

for "antigen specific immune response" on page 7, lines 1-13; page 9, lines 14-15;

for "one adjuvant of said at least one adjuvant is bacterial DNA" on page 7, lines 3-5; page 26, lines 11-15; page 99, Example 34; original claim 1; and, page 108, Table 37;

for the concept of "an adjuvant which is not bacterial DNA" and which is encoded by a polynucleotide, on page 36, lines 17-18;

for the concept of different antigens used with bacterial DNA: page 99, lines 1-19;

for "passing through" on page 39, line 18;

for the concept of multiple adjuvants used wherein one adjuvant is CpG1: original claim 1 and page 108, Table 37, demonstrating use of CpG1 and CT together;

and, elsewhere throughout the specification.

Support for the amendments to claim 4, is found, for example, as follows:
for "wherein said bacterial DNA is CpG1" on page 99, Example 34 and page 108, Table 37;
for the concept of different antigens used with CpG1: page 99, Example 34 (DT and CpG1);
page 108, Example 38 (SLA and CpG1);
and, elsewhere throughout the specification.

Claims 9-14, 19-26, 28, 30-32, 35, 36, 39-41, 44, 55-58, 72 and 75-77 were amended for grammatical reasons.

Support for the amendments to claim 80 is found, for example, as follows:
for "antigen specific immune response" on page 7, lines 1-13; page 9, lines 14-15;
for "one adjuvant of said at least one adjuvant is bacterial DNA" on page 7, lines 3-5; page 26,
for the concept of "an adjuvant which is not bacterial DNA" and which is encoded by a polynucleotide, on page 36, lines 17-18; lines 11-15; page 99, Example 34; original claim 1; page 108, Table 37;
for the concept of "an adjuvant which is not bacterial DNA" and which is encoded by a polynucleotide, on page 36, lines 17-18;
for the concept of different antigens used with bacterial DNA: page 99, lines 1-19;
for the concept of multiple adjuvants used wherein one adjuvant is CpG1: original claim 1 and page 108, Table 37, demonstrating use of CpG1 and CT together;
and, elsewhere throughout the specification.

Support for the amendments to claim 81 is found, for example, as follows:
for "wherein said bacterial DNA is CpG1" on page 99, Example 34 and on page 108, Table 37;
for the concept of different antigens used with CpG1: page 99, Example 34 (DT and CpG1) and on page 108, Example 38 (SLA and CpG1);
and, elsewhere throughout the specification.

Claims 87 and 90 were amended for grammatical reasons.

Support for the amendments to claim 93 are found, for example, as discussed above for claims 1, 4, 80 and 81; and, elsewhere throughout the specification. Claim 93 was also amended to more clearly claim the invention.

Claims 94 and 95 were amended for grammatical reasons.

Support for the amendments to claim 96 is found, for example, as follows:

for "wherein said bacterial DNA is CpG1" is found, for example, on page 99, Example 34 and page 108, Table 37;

for the concept of different antigens used with CpG1: page 99, Example 34 (DT and CpG1) and on page 108, Example 38 (SLA and CpG1);

and, elsewhere throughout the specification.

Support for the amendments to claim 99 is found, for example, in claim 93 and elsewhere throughout the specification. Claim 99 was also amended for grammatical reasons and to more clearly claim the invention.

Support for new claims 128-136 is found, for example, on page 37, lines 3-7, and, elsewhere throughout the specification.

No new matter is believed to have been added. The amendments made reflect, in part, the guidance offered by the Examiner in PTO Paper No. 27 and in the Advisory Action, mail dated December 18, 2003. In view of the amendments and following remarks, reconsideration of the rejections and withdrawal thereof is respectfully requested.

Advisory Action

This amendment and reply is substantially the same as the After Final amendment filed November 14, 2003 under 37 CFR § 1.116 and not entered on the grounds the proposed amendments raised new issues requiring further search and consideration. In view of the new issues requiring further search and consideration, the Office is reminded that it would not be proper to make final a first Office Action in a continuing application where that application contains material which was presented in the earlier application after final rejection but was denied entry because A) new issues were raised that required further consideration and/or search, or B) the issue of new matter was raised. (See, MPEP § 706.07(b)).

In the Advisory Action, the Examiner raises several issues regarding the claims submitted in the After Final Amendment. The following comments to the issues raised in the Advisory Action are offered in the interest of compact prosecution.

In the Advisory Action, the Examiner asserts the term "antigen-specific immune response" raises new issue under 35 U.S.C. § 112, first and second paragraphs, regarding the metes and bounds of the claims and enablement for the full breadth of the claim. Although the claims have not been officially rejected on these grounds, Applicants disagree with the assertion.

Applicants note that support for the phrase "antigen specific immune response" is found, for example, on page 7, lines 1-13; page 9, lines 14-15; and, elsewhere throughout the specification. The specification amply demonstrates throughout that an immune response specific to the antigen utilized is induced using the methods described in the specification.

The Advisory Action asserts the proposed claims are not commensurate in scope with those as rejected in the Final Office Action. Applicants note that the claims were rewritten to more clearly claim the invention and were believed to overcome the rejections raised in the Final Office Action. In addition, contrary to the position of the Office, CpG is a species of bacterial DNA (See, specification page 99, lines 4-6, stating "As shown below, unmethylated CpG motifs (CPGs) representative of bacterial DNA do enhance the immune response and may be considered adjuvants.") Lastly, the Advisory Action states that "Moreover, DNA containing CpG is the adjuvant itself and does not serve to 'encode' an adjuvant as required in step (a) of

claims 1 and 80." In reply thereto, claims 1, 80 and 93 have been rewritten to clarify when the adjuvant is encoded by a polynucleotide.

Election/Restriction

Applicants acknowledge the finality of the restriction requirement. The Examiner noted on page 3 of the Office Action that, in an election of species, that amendment of the claims is not required pending the finding of an allowable generic claim, but that in the instant case, neither the generic nor the elected species has been found to be allowable.

Applicants have amended the claims partly along the lines suggested by the Examiner as suggested on page 5 of the Final Office Action, under the 35 U.S.C. § 112, first paragraph, rejection of the claims. It is believed the amendments put the generic claims in condition for allowance. Applicants respectfully request rejoinder and action on the non-elected and withdrawn species claims (claims 32-34, 37, 38, 42, 43, 47-54, 59-71, 73 and 74).

Priority

The Examiner concludes, based on evaluation of all the pertinent applications under 35 U.S.C. § 112, first paragraph, that the instant application is given the priority date of May 21, 1998, the filing date of the provisional application, based on the occurrence of the elected species sequestrin. However, Applicants disagree with this determination. The generic claims are entitled to a priority date of at least July 17, 1997, the filing date of USPN 5,980,898 (See, column 14, lines 13-29, for example) as previously explained.

Applicants assert the generic claims as amended herein are allowable. Applicants are not required to amend the claims to the elected species when a generic claim is allowable.

Interference

As discussed above, the instant application is entitled to a priority date of at least July 17, 1997. The claims as amended are believed to overcome the rejection under 35 U.S.C. § 112, first paragraph, as discussed below. Since the claims as now amended are allowable, Applicants

request the declaration of interference with Khavari (USPN 6,087,341) and an interference with Tang *et al.* (USPN 6,348,450).

Khavari has a filing date of Feb. 12, 1998, approximately 7 months after the effective filing date of the instant application (July 17, 1997). Claims 102-116 were previously added to provoke an interference under 37 CFR § 1.607 (Amendment filed July 10, 2001). As previously discussed in the July 2001 amendment, claims 102-116 represent copies of claims 1-15 of the Khavari patent. The differences in claim language are inconsequential modifications ("organism" instead of "vertebrate", "penetration enhancer" instead of "irritant").

It is believed an appropriate interference count would be claim 102 of the instant application and Khavari claim 1. Thus, Khavari claims 1-16 and Applicants' claims 102-116 are directed to the same invention.

Applicants have also previously requested an interference also be declared with USPN 6,348,450 (Tang *et al.*) in the amendment filed March 14, 2002. Tang has a priority of August 13, 1997, approximately one month after the effective filing date of the instant application (July 17, 1997). Claims 117-127 were previously (amendment of March 14, 2002) added to provoke an interference with the Tang patent. As previously discussed in the March 2002 amendment, claims 117-127 represent copies of, *inter alia*, Tang patent claims 1-3, 16-19, 24-29, 35-39, 44-47 and 52. The differences in claim language are inconsequential modifications (for example, "organism" instead of "mammal," "polynucleotide expressing antigen, adjuvant or both with an operably linked regulatory region derived from a viral genome" instead of a "DNA viral vector which encodes a gene of interest") so as to accommodate the differences between the instant specification and the patent.

It is believed an appropriate interference count would be Tang patent claim 25 and Applicants' claim 117. Therefore, Tang patent claims 1-52 and Applicants' claims 117-127 would be directed to the same invention.

Consideration of the request to provoke an interference under 37 CFR § 1.607 between this application and USPNs 6,348,450 (Tang) and 6,087,341 (Khavari) is respectfully requested.

Information Disclosure Statements

The Examiner has asked for copies of all documents previously cited on the PTO 1449 forms by Applicants. Applicants will supply a copy of the documents as requested by the Examiner shortly after the filing of this amendment.

Claim Objections

The Examiner has objected to the claims because they encompass species which are not elected. Applicants respectfully traverse the objection.

The generic claims as amended herein are allowable and amendment of the claims is therefore not required. Withdrawal of the objections is respectfully requested.

Rejection under 35 USC § 112, first paragraph

The Examiner maintained the rejection of claims 1-31, 3, 36, 39-41, 44-46, 55-58, 72, 75-127 under 35 U.S.C. § 112, first paragraph, because "the specification while being enabled for a method of inducing an immune response in a mammal .....does not reasonably provide enablement for a method of immunization." Applicants respectfully traverse the rejection.

The Examiner argues and concludes (Office Action pages 5-8) it is the lack of the necessary guidance for producing the prophylactic immune response considered by the art to be immunizing which is the basis of the enablement rejection. Without acquiescing to the position of the Examiner, Applicants have amended the independent claims to now claim, *inter alia*, "a method of inducing an antigen specific immune response." The amended claim language tracks the claim language indicated by the Examiner to be enabling (Office Action, page 5). Support for the amendments to the claims has been discussed, above, and is incorporated herein. The amendments to the claims are believed to moot the rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

It is believed the application is in condition for examination on the merits and such is respectfully requested. If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the telephone number provided below.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and § 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. § 1.136(a)(3).

Date: **January 14, 2004**
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Respectfully submitted,
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